

## II. Rejection of Claims 9 to 13 under 35 U.S.C. 112

Claims 9 to 13 were rejected under 35 U.S.C. 112, first paragraph, for lack of an enabling description in the specification.

In accordance with the reasons on pages 2 and 3 of the Office Action, applicants have limited patent claim coverage of the claimed method in the proposed independent method claims 11 to 13 to administration of only melatonin.

The experimental results described on pages 3 to 6 of the originally filed specification were performed using melatonin as the effective ingredient. These results provide evidence of the effectiveness of a method of treating hyperinsulinemia as claimed in amended claims 11 to 13 by administration of melatonin.

Furthermore the Office Action admits on page 3 that the method limited to melatonin is supported by the specification.

For the foregoing reasons and because of the proposed changes in claims 11 to 13, entry of the proposed changes and withdrawal of the rejection of claims 11 to 13 under 35 U.S.C. 112 for lack of enablement is respectfully requested.

## III. Claims 9 and 10 were Rejected as Anticipated by Bailey, et al

If the proposed changes were to be entered, method claims 9 and 10 will have been canceled, obviating this rejection.

IV. Claims 11 to 13 were Rejected as Obvious from Bailey, et al,  
in view of Peschke, et al

Claims 9 to 13 were rejected as obvious under 35 U.S.C. 103 (a) from Bailey, et al, in view of Peschke, J. Peneal Res. 23, pp. 156-163 (1997). If the proposed changes are entered, claims 11 to 13 would be independent and include the features and limitations of claims 9 and 10. Proposed amended claims 11 to 13 are not obvious from Bailey, et al, in view of the Peschke article, which is dated July 11, 1997.

1. Applicants Swear Back of the Peschke article

Applicants have filed a Rule 131 affidavit, which accompanies this amendment to swear back of the Peschke article, namely the article by Peschke, et al, in J. Peneal Res. 23, pp. 156-163 (1997). This article is dated July 11, 1997 and thus could not establish a statutory bar to the claimed invention in the proposed amended claims 11 to 13 (the above-identified U.S. Patent Application is the U.S. National Stage of PCT/DE 09/01541, which in turn is based on German Patent Application DE 198 23 829.0, filed May 28, 1998).

The Declaration swearing back of the Peschke reference is signed by two of the inventors of the above-identified application and also by Officers of Jenapharm GmbH & Co. Both inventors are employed by Jenapharm GmbH & Co, which owns 100 % of the above-identified U.S. Patent Application. In addition, both inventors are co-authors of the above-identified Peschke article in

J. Peneal Res.

Both co-authors of the Peschke article swear that the invention of the above-identified application was invented before publication of the Peschke article. In the Declaration the Peschke article is designated with its "XP" number, namely XP-000866214. This XP number appears on the upper left hand corner of the first page of the copy of the article filed with the Information Disclosure Statement filed on January 24, 2003. Furthermore Germany is a WTO country and thus the provisions of 37 C.F.R. 1.131 are satisfied in that regard.

Thus the Peschke article is not a valid reference that can be combined with Bailey, et al, to reject the claimed invention under 35 U.S.C. 103 (a).

2. Bailey, et al, Contains Teaching that Would Lead Away  
from the Claimed Invention

Furthermore references that contain teaching that would lead on away from a claimed invention should not be combined with other references to reject the claimed invention under 35 U.S.C. 103 (a). For example, the Federal Circuit Court of Appeals has said:

"In determining whether such a suggestion [of obviousness] can fairly be gleaned from the prior art, ..It is indeed pertinent that these references teach against the present invention. Evidence that supports, rather than negates, patentability must be fairly considered." *In re Dow Chemical Co.*, 837 F.2nd 469,473, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988). Also see M.P.E.P. 2145 . X.

Bailey, et al, contains teaching that would lead one skilled in the art away from the claimed invention. This negative teaching should not be ignored. One skilled in the art would be discouraged from using melatonin to inhibit insulin release by administering to a living being or from preparing pharmaceutical compositions for that purpose. The last paragraph on page 24 of Bailey, et al, discloses "In vivo" studies of administration to melatonin to rats. It was found that plasma insulin levels were *not significantly changed*, although there was a slight apparent lowering of two out of five measured values shown in Fig. 3. Also glucose levels for the five measured values were not lowered at all. Also note the discussion regarding *in vivo* administration of melatonin on page 26, next to last paragraph, of the Bailey reference.

Thus Bailey, et al, contains teaching that would lead one skilled in the art to find that an effective treatment of hyperinsulinemia by administering melatonin or a pharmaceutical composition containing melatonin was surprising and unexpected.

For the foregoing reasons and because of the proposed changes in claims 11 to 13, entry of the proposed changes and withdrawal of the rejection of claims 11 to 13 under 35 U.S.C. 103 (a) from Bailey, et al, in view of Peschke, J. Peneal Res. 23, pp. 156-163 (1997) is respectfully requested.

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,

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